UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ILLINOIS

MARGARET SCHEFDORE, Plaintiff, v. WYETH, LLC, f/k/a WYETH, INC., and WYETH PHARMACEUTICALS, INC., PFIZER, INC., PHARMACIA & UPJOHN COMPANY LLC, PHARMACIA CORPORATION, GREENSTONE, LLC, SOLVAY PHARMACEUTICALS, INC., previously known as REID ROWELL, INC., and ORTHO-MCNEIL PHARMACEUTICAL INC. Defendants.	)	CASE NO.:_____ Hon. Judge:_____ **Jury Trial Demanded**

PERSONAL INJURY COMPLAINT

NOW COMES, Plaintiff, MARGARET SCHEFDORE (f/k/a Margaret Meseko hereinafter "SCHEFDORE" or "Plaintiff") by and through her undersigned counsel of record, and upon knowledge and belief as to all allegations of which she so possesses knowledge and upon information and belief as to all other allegations, complains of Defendants**,** WYETH, LLC, f/k/a WYETH, INC., and WYETH PHARMACEUTICALS, INC., PFIZER, INC., PHARMACIA & UPJOHN COMPANY, LLC, PHARMACIA CORPORATION, GREENSTONE, LLC, SOLVAY PHARMACEUTICALS, INC., previously known as REID ROWELL, INC., and ORTHO-MCNEIL PHARMACEUTICAL INC. (hereinafter "Defendants" or "Manufacturing Defendants") and in support thereof alleges as follows:

PARTIES

a. PLAINTIFF

1. Plaintiff is a woman who consumed hormone therapy medication and was personally injured by such products.

b. DEFENDANTS

2. Defendant, **WYETH LLC,** f/k/a Wyeth, Inc., and Wyeth Pharmaceuticals, Inc., (hereinafter "Wyeth") is a limited liability company, the sole member of which is Pfizer LLC, the sole member of which is Pfizer, Inc. which is a Delaware Corporation with its principal places of business in New York, which is the location where Pfizer's high level officers direct, control, and coordinate the corporation's activities. Upon information and belief, a merger between defendant Pfizer, Inc. and Wyeth has made defendant Pfizer, Inc. responsible for the obligations, debts and liabilities of Wyeth.

3. On or about March 11, 2002, the name of American Home Products Corporation ("AHPC") changed to Wyeth. On or about March 22, 2002, Wyeth-Ayerst Pharmaceuticals, Inc. changed its name to Wyeth Pharmaceuticals, Inc., a wholly owned subsidiary of Wyeth. On or about June 30, 2001, Wyeth-Ayerst Laboratories Company ("WALC") was merged into AHP Subsidiary Holding Corporation ("AHPSHC") and ceased to exist as a separate entity. On or about January 31, 2007, AHPSHC was merged into Wyeth. On or about November 9, 2009, Wyeth converted from a Delaware Corporation to a Delaware Limited Liability Company known as Wyeth LLC. Wyeth LLC is therefore the legal successor in interest to Wyeth, AHPC, AHPSHC and WALC, and is fully liable for all the acts and omissions alleged herein committed by its various subsidiaries and predecessors in interest. At all times material hereto, Wyeth, LLC and its various subsidiaries and predecessors in interest were engaged in the business of testing,

developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, hormone therapy products for ultimate sale and/or use in the United States of America, including but not limited to the State of Illinois as well as in various foreign jurisdictions. Defendant may be served with process through its registered agent at:

WYETH LLC, f/k/a Wyeth, Inc. and Wyeth Pharmaceuticals, Inc.
Prentice Hall Corporation
33 North LaSalle Street
Chicago, IL 60602-2607

4. Defendant, **PFIZER, INC**., is a Delaware corporation with its principal place of business in New York, which is the location where Pfizer's high level officers direct, control, and coordinate the corporation's activities. Pfizer is licensed to do business in all states of the United States of America including the State of Illinois. Upon information and belief, a merger exists between Pfizer, Inc., Pharmacia & Upjohn Company, and Pharmacia Corporation and as a result, Pfizer, Inc. is legally and factually responsible for all obligations, debts and liabilities of Pharmacia & Upjohn Company and Pharmacia Corporation. Pfizer, Inc. is the successor in interest and real party to Pharmacia & Upjohn Company and Pharmacia Corporation. At all times relevant hereto, Pfizer, Inc., was engaged in, inter alia, the business of designing, manufacturing, producing, testing, inspecting, mixing, labeling, marketing, advertising, selling, promoting, and/or distributing hormone therapy drugs, including the drug Provera, generic estrogen and generic medroxyprogesterone acetate (MPA) for ultimate sale and/or use in the United States of America, including but not limited to the State of Illinois as well as in various foreign jurisdictions. Defendant may be served with process through its registered agent at:

PFIZER, INC.
C T Corporation System
208 South LaSalle Street, Suite 814
Chicago, IL 60604-1101

5. Defendant, **PHARMACIA & UPJOHN COMPANY LLC,** is a limited liability company whose sole member is Pharmacia and Upjohn LLC, whose sole member is Pharmacia, which is a wholly owned subsidiary of Pfizer, Inc, which is a Delaware Corporation with its principal places of business in New York, which is the location where Pfizer's high level officers direct, control, and coordinate the corporation's activities. At all times relevant hereto, Pharmacia & Upjohn Company LLC was engaged in, inter alia, the business of designing, manufacturing, producing, testing, inspecting, mixing, labeling, marketing, advertising, selling, promoting, and/or distributing hormone therapy drugs, including the drug Provera, generic estrogen and generic medroxyprogesterone acetate (MPA) for ultimate sale and/or use in the United States of America, including but not limited to the State of Illinois as well as in various foreign jurisdictions. Defendant may be served with process at:

PHARMACIA & UPJOHN COMPANY LLC
C T Corporation System
208 South LaSalle Street, Suite 814
Chicago, IL 60604-1101

6. Defendant, **PHARMACIA CORPORATION** is a wholly owned subsidiary of Pfizer, Inc. Since it is a wholly owned subsidiary of Pfizer, Inc., Pharmacia Corp. is a resident and citizen of the State of New York with its principle place of business in New York, which is the location where this Defendant's high level officers direct, control, and coordinate the corporation's activities. At all relevant times, Pharmacia Corp. was licensed to do business in all states of the United States of America including the State of Illinois. At all relevant times, this Defendant was engaged in the design, manufacture, production, testing, inspection, mixture,

labeling, marketing, advertising, sales, promotion, and/or distribution of hormone therapy drugs including the drug Provera for ultimate sale and/or use in the United States of America, including but not limited to the State of Illinois as well as in various foreign jurisdictions. Defendant may be served with process at:

PHARMACIA CORPORATION
C T Corporation System
208 South LaSalle Street, Suite 814
Chicago, IL 60604-1101

7. Defendant, **GREENSTONE LLC**, (hereinafter "GREENSTONE"), is a wholly-owned subsidiary of Pfizer, Inc. Since it is a wholly owned subsidiary of Pfizer, Inc., Greenstone LLC is a resident and citizen of the State of New York with its principle place of business in New York, which is the location where this Defendant's high level officers direct, control, and coordinate the corporation's activities. At all relevant times Greenstone was licensed to do business in all states of the United States of America including the State of Illinois. Upon information and belief, Greenstone is a Delaware corporation with its principal place of business in New Jersey. Further, Greenstone either is now or was during the relevant time frame, a subsidiary of Defendants Pharmacia / Upjohn / Pfizer and such Defendants are responsible for all liabilities and obligations of this Defendant. Defendant has already been served with process. At all relevant times, this Defendant was engaged in the design, manufacture, production, testing, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of hormone therapy drugs including a generic medroxyprogesterone acetate (MPA) for ultimate sale and/or use in the United States of America, including but not limited to the State of Illinois as well as in various foreign jurisdictions. Defendant may be served with process at:

GREENSTONE, LTD.
C/o Pfizer Inc.
C T Corporation System
208 South LaSalle Street, Suite 814
Chicago, IL 60604-1101

8. Defendant, **SOLVAY PHARMACEUTICALS, INC.,** previously known as **REID ROWELL, INC**., at all relevant times was licensed to do business in all states of the United States of America including the State of Illinois. At all relevant times, this Defendant was engaged in the design, manufacture, production, testing, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of hormone therapy drugs including estrogen therapies for ultimate sale and/or use in the United States of America, including but not limited to the State of Illinois as well as in various foreign jurisdictions. Defendant may be served with process at:

SOLVAY PHARMACEUTICALS, INC.
previously known as REID ROWELL, INC
Corporate Headquarters
901 Sawyer Road
Marietta, GA 30062

9. Defendant, **ORTHO-MCNEIL PHARMACEUTICAL INC.** at all relevant times was licensed to do business in all states of the United States of America including the State of Illinois. Upon information and belief, Ortho-McNeil Pharmaceutical Inc. is a wholly owned subsidiary of Johnson and Johnson Inc. Ortho-McNeil Pharmaceutical Inc. is a resident and citizen of the State of New Jersey with its principal place of business and headquarters in Raritan, New Jersey. At all relevant times, this Defendant was engaged in the design, manufacture, production, testing, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of hormone therapy drugs including estrogen therapies for ultimate sale and/or use in the United States of America, including but not limited to the State of

Illinois as well as in various foreign jurisdictions. Defendant may be served with process at:

Ortho-McNeil Pharmaceuticals
C T Corporation System
208 South LaSalle Street, Suite 814
Chicago, IL 60604-1101

JURISDICTION AND VENUE

10. Jurisdiction over this matter is proper in this Court pursuant to 28 U.S.C.A. § 1332 because of diversity of citizenship of the parties and because the amount in controversy is in excess of $75,000 exclusive of costs and interest. Plaintiff is a resident of Kane County, Illinois. Venue in this Court is proper under 28 U.S.C. § 1391.

FACTUAL BACKGROUND

(a) DEFENDANTS

11. Plaintiff brings this action to recover damages for personal injuries against the following Manufacturing Defendants of hormone therapy medications for their design, promotion, testing, manufacturing, labeling, distribution, promoting and sale of the following described hormone therapy drugs (hereinafter referred to collectively as "hormone therapy") including:

(i) **Wyeth LLC, f/k/a Wyeth, Inc. and Wyeth Pharmaceuticals, Inc.,** (hereinafter Wyeth) for a conjugated equine estrogenic compound (hereinafter CEE) sold under the brand name Premarin; a Medroxyprogesterone acetate (MPA), which is a synthetic compound in the same chemical class as the natural hormone progesterone, (hereinafter MPA) sold under the brand name Cycrin and generic MPA as well as a combination of CEE and MPA sold under the brand names Prempro and Premphase;

(ii) **Pfizer, Inc., Pharmacia & Upjohn Company LLC, Pharmacia Corporation and Greenstone LLC** (hereinafter Pfizer) for a MPA sold under the brand name Provera, a generic MPA, as well as an estrogen hormone therapy Ogen. Defendants manufactured, marketed, promoted and sold Provera and generic MPA to be used in conjunction with Wyeth's CEE Premarin and other estrogen therapies.

(iii) **Solvay Pharmaceuticals, Inc**., formerly known as Reid Rowell, Inc. (hereinafter Solvay) for an estrogen hormone drug manufactured, marketed, promoted and sold under the name Estratest to be used in conjunction with MPA hormone therapies, and Prometrium.

(iv) **Ortho-McNeil Pharmaceutical, Inc. a wholly owned subsidiary of Johnson and Johnson Inc.**, (herein Ortho-McNeil) for a combination pill containing an estrogenic compound and a progestin sold under the brand name of Ortho-Prefest. Ortho-McNeil manufactured, marketed, promoted and sold Ortho-Prefest for use as a combination pill.

(b) PLAINTIFF

12. Plaintiff Margaret Schefdore is a resident and citizen of the state of Illinois. Plaintiff developed infiltrating lobular breast cancer that was hormone receptor positive during, after, and as a result of taking hormone therapy drugs including Estratest, Premarin, Provera, Prometrium, MPA by Greenstone, Prempro and Orthoprefest. Due to her breast cancer, Plaintiff underwent breast surgery, radiation therapy, chemotherapy and long-term use of Arimidex.

13. Hormone therapy medication is marketed to women who are going through menopause. Menopause describes a time in the natural aging process of a woman when her body's production of the natural hormones estrogen and progesterone is dramatically reduced. There are physical consequences to a woman when her levels of estrogen and progesterone drop so dramatically. These consequences include symptoms like mood swings, hot flashes, loss of bone density, depression, irritability, night sweats and forgetfulness. These symptoms range from severe and disabling in some women to a minor inconvenience form other women.

14. In 1942, Ayerst, the predecessor to Wyeth and Wyeth Pharmaceuticals, (and hereinafter Wyeth) received approval for Premarin, which is a conjugated equine estrogen made from the urine of pregnant mares. Premarin has remained chemically unchanged until today.

Wyeth began marketing its product as a hormone replacement product, to replace the natural female hormone estrogen.

15. Since 1942, Wyeth has vigorously promoted its menopausal hormone therapy products using a variety of marketing messages that emphasize the use of these medications long-term. Indeed, the 1973 key marketing statement for Premarin was "start her on, keep her on". Even as late as 1991, Wyeth still represented that "protection continued only as long as estrogen therapy continued."

16. To get this message out to the patients and the doctors, Wyeth has used the following marketing methods to promote its products:

A. Sponsoring medical journal articles about the benefits of its products;

B. Detailing /sales representatives calling on and encouraging physicians to prescribe the drugs;

C. Sponsored continuing medical education programs discussing the benefits of its products;

D. Hiring experts in the field to speak to other physicians either one on one or in small group meetings;

E. Press releases;

F. Direct to consumers advertisements about the products;

G. Advertisements directed to physicians in medical journals and materials; and

H. Sponsoring medical and pseudo-medical organizations to make statements supporting the use of the products.

17. Wyeth has also extensively represented through the methods listed above, the negative health effects of menopause ranging from symptoms like hot flashes, night sweats and mood changes to an increased risk of life changing and life threatening conditions like cardiovascular problems, osteoporosis and dementia. Through its marketing and advertising

efforts, Wyeth convinced doctors and patients that menopause was not the natural process of aging, but instead turned this process into a disease in need of drug treatment.

18. Wyeth's attempts to disguise menopause as a disease started decades ago. In 1962, Dr. Robert Wilson, a New York, gynecologist, published an article in the *Journal of the American Medical Association* (*JAMA*), that claimed estrogen taken during menopause could **reduce** breast and genital cancers. A few years later, in 1966, Dr. Wilson published a bestseller book entitled *Feminine Forever*. In *Feminine Forever*, Dr. Wilson recommended estrogen as the "cure" for "the tragedy of menopause." He argued that women who use the drugs "will be much more pleasant to live with and will not become dull and unattractive." In writing about the menopause condition, which he termed the "deficiency disease," Dr. Wilson wrote that "aside from keeping a woman sexually attractive and potent...estrogen preserves the strength of her bones, the glow of her skin, the gloss of her hair...Estrogen makes women adaptable, even-tempered, and generally easy to live with." Dr. Wilson asserted that estrogen *prevents* breast and genital cancers, such as endometrial cancer (i.e., cancer of the uterine lining). Unbeknownst to readers, Dr. Wilson was financially supported by Wyeth to write, publish, promote and market this book. While disguised as an independent project, *Feminine Forever*, was nothing more than a bestselling promotional piece for Wyeth's estrogen products. There was no reliable science to support Dr. Wilson's assertions or claimed benefits.

19. Soon after the publication of Dr. Wilson's book, Wyeth' sales force began to distribute the book to physicians throughout the country. Wyeth spent thousands of dollars supporting Dr. Wilson's promotional book tour and sales of Premarin increased dramatically.

20. In 1974 and 1975, Wyeth started a round of advertising that recommended Premarin as an alternative treatment to tranquillizers for the treatment of symptomatic or mild

depression caused by menopause. In a print advertisement that Wyeth published in the October 13, 1975, edition of *JAMA*, Wyeth claimed that "tension, irritability, headaches, undue fatigue, depression and insomnia," when caused by declining menopausal estrogen levels, may be relieved with Premarin. Additionally, at the top of the advertisement, in large print, Wyeth advised doctors, "Almost any tranquilizer might calm her down . . . but at her age, estrogen may be what she really needs." The 1975 advertisements stated: "in the treatment of middle-aged depression, there may be one thing to add… Premarin." Again no clinical studies or reliable science supported these representations.

21. In 1977, the Food & Drug Administration (FDA) issued a statement confirming that estrogen therapy should not be used to treat simple nervousness during menopause and that there was no scientific support for any representation that such therapy could keep a woman feeling young or her skin soft.

22. By the mid-70s more than 30 million prescriptions for Premarin were being written every year, eventually making it the fifth most frequently prescribed drug in the United States.

23. Then the first hormone therapy health epidemic arose. In the New England Journal of Medicine (NEJM) in 1975, two articles appeared that linked estrogen therapy to a significantly increased risk of women developing endometrial cancer. Quickly physicians stopped prescribing Premarin for women with intact uteri. Estrogen sales plummeted and by 1979, the only approved use of estrogen was for treatment of hot flashes and vaginal dryness.

24. In 1979, Dr. Robert Greenblatt published an article in the *Journal of Geriatrics Society* which reported that "*estrogen related uterine cancer can be avoided if progesterone is added to the regimen*". Wyeth and the other drug manufacturers immediately started promoting

combination hormone therapy.

25. In order to obtain a patent on the product, Pfizer developed a synthetic hormone product called Medroxyprogesterone Acetate or MPA that was marketed under the brand name Provera. This drug does not have the same chemical or pharmacological effect as the natural hormone progesterone. From the early 1980s until 1995, a common combination prescription was the use of Premarin with Provera. Indeed, in 1985, the Pfizer advertising campaign for Provera was a color advertisement featuring Premarin and Provera as the preferred hormone therapy combination.

26. Other drug companies also created alternate estrogen products as well as MPA products for use in hormone therapy including Wyeth, Greenstone, Barr, BMS and Reid Rowell.

27. In 1985, Wyeth added a new spin to the marketing of hormone therapy drugs by claiming that the drugs could help prevent bone loss. Wyeth hired a public relations firm to create public awareness of osteoporosis and learned that 77% of women had never heard of osteoporosis. As a result, Wyeth's public relations campaign informed women that osteoporosis is a devastating disease and that its estrogen drug, Premarin, could treat it. Soon, their public relations campaign created support for a National Osteoporosis Week and eventually, a National Osteoporosis Foundation (to which Wyeth contributed).

28. Wyeth also sought to claim that hormone therapy drugs, such as Premarin, could prevent or reduce cardiovascular disease. Indeed, Wyeth's sales representatives encouraged doctors to prescribe hormone therapy even if a woman was not having menopausal symptoms because of the therapy's purported cardiac benefits.

29. Wyeth claimed that the cardiac benefits of hormone therapy were proven by the Nurses Health Study. The Nurses Health Study, which was based on questionnaires of almost

122,000 female nurses, including 32,300 post-menopausal women. This study's results were published in 1985 and were clearly impacted by observational and selection bias since the population of nurses were health conscious and generally following better exercise and diet regiments than a general population. Moreover, the participants in The Nurses' Study were educated and compliant "patients"—actually nurses—who were more keenly aware of their health conditions and at a lower risk for heart disease regardless of hormone therapy. However, Wyeth ignored this obvious flaw and instead exaggerated the results to support its promotion of Premarin.

30. As a result of Wyeth's marketing efforts, between 1990 and 1995 Premarin became the most frequently dispensed prescription drug in the United States.

31. In approximately 1993, Wyeth distributed a videotape to consumers entitled, "*What every woman should know about Estrogen*." This videotape claimed to be a "seminar for women" and depicted a female doctor advising women about menopause and hormone therapy. Wyeth's video "seminar" warned of a wide variety of illnesses and ailments purportedly associated with menopause. Among other things, Wyeth represented that estrogen loss causes bones to become "brittle," skin to become "dryer," and sexual intercourse to become "painful and irritating."

32. While Wyeth's video was exhaustive in its warnings about menopause, it glossed over the dangers and risks associated with hormone therapy. In its "*What every woman should know about Estrogen*" video seminar, Wyeth also represented to women that estrogen provided "long term health protection" and should be continued indefinitely, even after short term menopausal symptoms, such as hot flashes, had subsided. When a purported consumer inquired how long Premarin should be taken, Wyeth's doctor-spokesperson responded "anywhere from

five to ten years in order to get protection from long term problems." And, with regard to breast cancer risks, Wyeth represented to women, through its video "seminar" that the benefits of taking estrogen "far outweigh[ed]" the risks for women unless they faced a particularly high risk of breast cancer.

33. In 1994, Wyeth got approval for its next marketing blockbuster: combination hormone therapy in a single pill. Prempro is an oral medication that combines the estrogenic compound CEE with the progestin MPA in a single pill taken one time per day. A similar Wyeth product containing the same combination of compounds is brand named Premphase. Premphase delivers both CEE and MPA for only part of the monthly regime and then CEE alone without the MPA component for the rest of the month. Wyeth now had multiple hormone therapies in the "Premarin family of products" to market and promote.

34. Soon after introduction of Prempro, Wyeth agreed to fund a four year heart disease prevention trial, called HERS: Heart and Estrogen/Progestin Replacement Study. Wyeth touted the study as one that would show that that Prempro (its specific combination of CEE and MPA hormone therapy) prevented heart disease in women who were at high risk for heart disease. Wyeth was seeking FDA approval of the use of Prempro to prevent or reduce the risk of heart disease. But in 1998, the HERS investigators reported that hormone therapy did not reduce the rate of coronary heart disease events in women with heart disease and in fact dramatically increased the risk of heart disease and heart attack in those women, especially in the first year. The HERS results were immediately minimized or ignored by Wyeth and its sales representatives.

35. With no actual science to support its assertions, Wyeth continued an aggressive marketing plan with promotion directly to the patients. Beginning in early 1999, Wyeth even

distributed a brochure to women through the waiting rooms of physicians' offices, that claimed, "Menopause isn't gone in a flash — its debilitating consequences can affect the rest of your life." The promotional brochure also directed women to "Take a few minutes to think about the rest of your life" and listed a number of conditions which neither Prempro nor Premarin had been approved by the FDA to treat, including Alzheimer's disease, vision problems, tooth loss, heart disease, and colon cancer.

36. In a magazine advertisement that featured model Lauren Hutton, Wyeth made a rash of similar claims, suggesting that its hormone therapy drugs were appropriate for treating or preventing, among other things, memory loss, colon cancer, and age-related vision loss. In the March 19, 2000, edition of *Parade Magazine,* Wyeth spokesperson Lauren Hutton (who was not identified as a Wyeth spokesperson) was asked what she did to look good and feel fit and she answered: "[M]y number 1 secret is estrogen. It's good for your moods, it's good for your skin. If I had to choose between all my creams and makeup for feeling and looking good, I'd take the estrogen."

37. A cornerstone of the marketing Wyeth program was promotion of hormone therapy for long-term use of indefinite duration. Specifically, *JAMA* reported that:

> In 2000, 46 million prescriptions were written for Premarin (conjugated estrogens), making it the second most frequently prescribed medication in the United States and accounting for more that $1 billion in sales, and 22.3 million prescriptions were written for Prempro (conjugated estrogens plus medroxyprogestrone acetate). While US Food and Drug Administration-approved indications for hormone therapy include relief of menopausal symptoms and prevention of osteoporosis, *long-term use has been in vogue to prevent a range of chronic conditions, especially heart disease.*
> (Emphasis added.)

38. Wyeth continued to press the FDA to approve the use of Prempro to prevent or reduce the progression of heart disease in post-menopausal women. The FDA did not believe

there was sufficient scientific evidence to support such an indication/usage of the drug and denied Wyeth's request without reliable science from a controlled study to support the assertions. Even though the FDA had specifically not approved the use of Prempro for the prevention or improvement of heart disease, Wyeth continued to promote Prempro as having this benefit and even represented to physicians that Prempro reduced cardiovascular mortality by 50%.

39. In the early 1990s, the Women's Health Initiative Study (WHI) was thus born. Conducted by the National Institutes of Health (NIH) and supported by Wyeth, this large scale, controlled study was designed to definitively allay any question about Prempro's heart, osteoporosis and mental cognition benefits.

40. While Wyeth waited for the WHI study researchers to collect their data and reach their conclusions, the drug maker's overzealous hormone therapy marketing effort continued. At least until mid-2002, Wyeth distributed a hormone therapy promotional brochure targeted for women consumers. The front cover stated: "Starting your Hormone Replacement Therapy (HRT)" and encouraged a woman to "Say yes to PREMPRO." The brochure contained testimonial statements from women taking Prempro, such as, "I wanted an HRT that was established, time tested, and had a successful track record. I'm delighted with PREMPRO" and "With PREMPRO, I know I've taken action to protect my health— and that's truly empowering." The unbalanced nature of Wyeth's marketing efforts is typified by the inadequate warnings contained in the "Side Effects" section of Wyeth's "Say yes to PREMPRO" brochure. In the warnings section, Wyeth only relate the risk of uterine cancer (associated with estrogen-only therapy), worsening diabetes, nausea, abdominal pain, irregular bleeding, headache, hair loss, and breast tenderness.

41. On July 9, 2002, the National Heart, Lung and Blood Institute ("NHLBI"), a federal agency and part of the National Institutes of Health ("NIH"), halted the WHI study because the investigators concluded that, under the circumstances, the risks of taking Prempro outweighed its benefits. The scientific papers discussing the results of the WHI study provided the most comprehensive published data evaluating the risk and benefits of this drug combination of CEE and MPA. In July of 2002, the published results of the WHI provided the scientific and medical communities with important (although preliminary) information as to the varied and overwhelming risks associated with hormone therapy. Since July of 2002 there have been a number of additional findings and studies published and other studies evaluating these risks are ongoing currently.

42. The results of the WHI study and other studies like it, contradict the scientific and medical assertions that all Manufacturing Defendants had made for decades about their respective products. Manufacturing Defendants told the community of medical physicians who consistently prescribed these medications that the risks of these drugs were minimal and that there were great benefits ranging from symptom relief to the prevention of life threatening medical conditions like heart disease and osteoporosis.

43. The Women's Health Initiative (WHI) was a study that focused on defining the risks and benefits of strategies that could potentially reduce the incidence of heart disease, breast and colorectal cancer, and fractures in post-menopausal women. Between 1993 and 1998, the WHI enrolled 161,809 post-menopausal women volunteers in the age range of 50 to 79 years. The study was conducted at 40 clinical centers in the United States and was scheduled to last for 15 years. Participants in the combination therapy arm of the WHI study received Prempro because it contained both the progestin MPA as well as the estrogenic compound Premarin. The

Prempro arm of the WHI involved 16,608 women ages 50 to 79 years with an intact uterus. An important objective of the trial was to examine the effect of this combination pill on the prevention of heart disease and hip fractures, and any associated change in risk for breast and colon cancer.

44. In 2000 and again in 2001, WHI investigators complied with a recommendation from the study's Data and Safety Monitoring Board (DSMB) to inform participants of a small increase in heart attacks, strokes, and blood clots in women taking hormones. The DSMB, an independent advisory committee charged with reviewing results and ensuring participant safety, found that the actual number of women having any one of these events was small and did not cross the statistical boundary established to ensure participant safety. Therefore, the group recommended continuing the trial due to the still uncertain balance of risks and benefits.

45. At the DSMB's meeting on May 31, 2002, the data review confirmed that the number of cases of invasive breast cancer in the estrogen plus progestin group had crossed the boundary established as a signal of increased risk. The DSMB's May 31, 2002, recommendation to stop the trial was based on the finding of increased breast cancer risk, supported by the evidence of overall health risks exceeding any benefits. On July 8, 2002 participants started receiving letters informing them about the results and telling them that they should stop study medications.

46. The WHI Study found that for the Prempro arm, when compared to placebo, there was an overall increased risk of the following adverse events:

(i) 41 % increase in strokes;

(ii) 29 % increase in heart attacks;

(iii) 200 % increase in venous thromboembolism (blood clots);

(iv) 22 % increase in total cardiovascular disease; and

(v) 26 % increase in breast cancer.

The WHI Study concluded that the "Overall health risks exceeded benefits from use of combined estrogen plus progestin for an average 5.2-year follow-up among healthy post-menopausal US women." The Study also found that the combination hormone regimen should not be initiated or continued for primary prevention of coronary heart disease.

47. Because of the importance of the report from the WHI investigators on the estrogen plus progestin study, the study was released early to the public on July 9, 2002, as an expedited article on the *JAMA* Web site. In commenting on the study's findings, NHLBI Director, Dr. Claude Lenfant, was unequivocal in his own conclusions:

> The cardiovascular and cancer risks of estrogen plus progestin outweigh any benefits—and a 26 percent increase in breast cancer risk is too high a price to pay, even if there were a heart benefit. Similarly, the risks outweigh the benefits of fewer hip fractures.

48. Dr. Jacques Roussow, acting director of the WHI and lead author of the JAMA article, summarized the risks of combination hormone therapy in very straightforward manner as he explained the statistical significance of the study results:

> The WHI results tell us that during 1 year, among 10,000 post-menopausal women with a uterus who are taking estrogen plus progestin, ***8 more will have invasive breast cancer, 7 more will have a heart attack, 8 more will have a stroke, and 18 more will have blood clots, including 8 with blood clots in the lungs***, than will a similar group of 10,000 women not taking these hormones. This is a relatively small annual increase in risk for an individual woman. Individual women who have participated in the trial and women in the population who have been on estrogen and progestin should not be unduly alarmed. However, even small individual risks over time, and on a population-wide basis, add up to ***tens of thousands of these serious adverse health events***.
> (Emphasis added)

49. Hormone therapy poses substantial health risk with little or no corresponding benefit. This is especially true of the use of estrogens combined with synthetic progestins. All Defendants knew (or should have known) of those risks. However, all Manufacturing Defendants named in this suit intentionally and knowingly marketed, promoted and encouraged the combination use of these two hormone drugs. Importantly, no Defendant ever conducted a controlled, long-term or well designed study to monitor or evaluate the risks of combination hormone therapy. Further no Defendant ever adequately or competently studied the relative effectiveness versus risk of lowering the recommended dose of the combination drugs or of encouraging such combination use only for short durations. Every defendant knew of the significant risks associated with combination therapy and failed to appropriately warn of such risks. These risks include breast cancer, ovarian cancer, heart attacks, strokes, deep vein thromboembolisms, pulmonary embolisms, gallbladder cancer and auto-immune diseases (such as lupus and scleroderma).

50. **Blood Clot risks,** hormone therapy causes blood clots which, depending on where they occur or end up, result in strokes, heart attacks, thromboembolisms, and pulmonary embolisms. Manufacturing defendants never adequately or appropriately warned physicians or users that estrogen therapy could cause or contribute to this risk.

51. **Breast cancer risks**, the connection between hormone therapy usage and breast cancer found in the WHI studies were confirmed by a similar study conducted in the United Kingdom. The August 9, 2003, issue of *Lancet*, reported on the conclusions reached by *The Million Women Study* — a major research effort funded by Cancer Research UK — confirming that current and recent hormone therapy increases a woman's chance of developing breast cancer and that the risk goes up with duration of use. Scientists at the Cancer Research UK analyzed

data from over one million women between the ages of 50 and 64. Researchers found that post-menopausal women using combination hormone therapy were twice as likely to develop breast cancer as non-users (a 100 per cent increase). Using the Million Women Study data, it is estimated that hormone therapy has caused more than 100,000 additional and unnecessary breast cancers in the United States of America alone.

52. Further, the initial WHI results were supplemented on June 25, 2003, by another article published in JAMA. This article confirmed that the WHI data found that in addition to stimulating the growth of breast cancer, combination hormone therapy makes breast tumors harder to detect, leading to dangerous delays in diagnosis. The article reported that breast abnormalities could develop soon after a woman starts taking hormone therapy. Consequently, the study's findings raise questions about the safety of even short-term hormone use. In the same June 25, 2003, issue that reported this study, JAMA also published an editorial by Dr. Peter H. Gann, a cancer epidemiologist at Northwestern University, who stated that this study represents "further compelling evidence against the use of combination estrogen plus progestin hormone therapy." Manufacturing defendants never adequately or appropriately warned physicians or users that estrogen therapy could cause or contribute to this risk.

53. **Ovarian Cancer risksm,** in the same JAMA edition as the publication of the original WHI results, another article appeared related to the risk of long-term use of estrogen-only therapy. This article detailed the National Cancer Institute Study which found that women who took estrogen therapy were more likely to develop ovarian cancer than those not on the hormone. The NCI study is reported at Lacey JV Jr., et al., *Menopausal hormone replacement therapy and risk of ovarian cancer.* (JAMA. 2002 Jul 17; 288(3):334-41.) In the study, NCI researchers followed 44,241 women for 19 years who were taking estrogen therapy only and

found that these women had a 60% higher risk of ovarian cancer than women who had never used estrogen therapy. The risk increased proportionately with longer duration of estrogen therapy use. Women who took estrogen therapy for 10 to 19 years had an 80% higher risk than those who did not take the pills. Those on estrogen therapy for 20 years or more were three times as likely to develop ovarian cancer as women who did not take it at all. Most of the NCI participants used Wyeth' brand of estrogen therapy, Premarin. Lead author of the NCI study, Dr. James V. Lacey, summarized the results of his study with the following statement:

> The main finding of our study was that post-menopausal women who used estrogen replacement therapy for 10 or more years were at significantly higher risk of developing ovarian cancer than women who never used hormone replacement therapy.

Dr. Lacey further underscored the implications of his NCI study, by explaining that the findings translate into one or two additional ovarian cancers each year per 10,000 women taking estrogen alone. In 2000, eight million American women took Premarin, the leading estrogen therapy pill. The Lacey study demonstrates that Premarin usage is responsible for up to 1,600 additional ovarian cancer cases in the year 2000 alone.

In October of 2003, the WHI Prempro trial produced a report with findings similar to the NCI study regarding ovarian cancer. In the October 1, 2003, issue of JAMA, WHI researchers reported that combination hormone therapy was associated with increased risk for ovarian cancer and combination hormone therapy caused a 58% increase in ovarian cancer rates.

Manufacturing defendants never adequately or appropriately warned physicians or users that estrogen therapy could cause or contribute to the development of ovarian cancer.

54. **Auto-Immune Disease risks**. Since 1995, Manufacturing Defendants have known that hormone therapy (including unopposed estrogen therapy) caused a statistically

significantly increased risk of auto-immune diseases including Lupus, Scleroderma and Raynaud's Phenomena. Manufacturing defendants never warned physicians or users of this association or risk.

55. **Gallbladder cancer risks**. Since 1997, Manufacturing Defendants knew (or should have known) that hormone therapy causes a statistically significant increased risk of gallbladder cancer in users. Manufacturing defendants never warned physicians or users of this association or risk.

56. **Arthritis risks**, Manufacturing Defendants were aware (or should have known) that hormone therapy causes a significant increased risk of incident arthritis. Manufacturing defendants never warned physicians or users of this association or risk.

57. **Asthma risks**, Manufacturing Defendants were aware (or should have known) that hormone therapy caused an increased risk of newly diagnosed asthma. Manufacturing defendants never warned physicians or users of this association or risk.

58. **General cancer risk**, In addition to the studies published in *JAMA, NEJM,* and other medical journals, a recent federal agency report also revealed that estrogen could be dangerous to women taking it as hormone therapy. On December 11, 2002, the National Institute of Environmental Health Sciences released its tenth annual report on carcinogens, which confirmed that estrogen is a "known human carcinogen."

59. **No real benefit,** It is now also clear that hormone therapy provides little real benefit beyond symptom alleviation. For even its approved indications, there were safer alternative medications that provided better results with less risk. Indeed, rather than providing any heart benefit or mental cognition benefit, hormone therapy actually dramatically increases the risk of heart attack and stroke, especially in the first year of use, and reduces a woman's

mental functioning. Hormone therapy has now also been associated with hearing loss and osteoarthritis.

60. **Cardiac benefits,** In the August 7, 2003, issue of *NEJM*, the WHI study continued to yield important information regarding the safety of hormone therapy use. The study found that combination hormone therapy does not protect the heart and may even increase the risk of coronary heart disease (CHD). Specifically, the WHI study found that combination hormone therapy usage was associated with a 24% overall increase in the risk of CHD (6 more heart attacks annually per 10,000 women using combination therapy) and a 81% increased risk of CHD in the first year after starting combination therapy.

61. **Osteoporosis benefits**, Manufacturing Defendants were aware (or should have known) that other therapies for osteoporosis, including Fosamax, provided better osteoporosis prevention and treatment benefits with less risk. On May 21, 2003, JAMA published another study studying the efficacy of estrogen plus progestin therapy (e.g., Prempro) for prevention of bone loss in elderly women. The study involved 373 women ages 65 to 90 who had either thinning bones or full-blown osteoporosis and took one of four treatments for three years: (i) combination hormone therapy alone, (ii) a bone-building drug, alendronate (which is sold under the brand name, Fosamax), (iii) combination hormone therapy with Fosamax, or (iv) a placebo. This study found that Fosamax alone was more effective than combination hormone therapy alone in combating osteoporosis. After three years, hipbone density had increased nearly 6 percent in women on hormone therapy with Fosamax, 4 percent in those on Fosamax alone, and 3 percent in the hormones-only group. Yet, manufacturing defendants continued to over-promote and exaggerate the hormone drugs' purported benefits.

62. **Increased mental function benefits,** On May 28, 2003, JAMA published another study on the effects of hormone therapy, this time focusing on the risk of Alzheimer's disease and other types of dementia. The study found that combination hormone therapy Prempro doubled the risk of dementia for woman who started hormones at age 65 or older. The Dementia study was based on a four-year trial involving 4,532 women at 39 medical centers, where half of the volunteers took placebo pills and half took Prempro. In four years, there were 40 cases of dementia in the Prempro group and 21 in the placebo group. Translated to an annual rate for the population-at-large, the results mean that for every 10,000 women 65 and older taking hormone therapy, there will be 45 cases of dementia a year with 23 of them attributable to hormone use. Dr. Sally A. Shumaker, the director of the dementia study and a professor of public health sciences at Wake Forest University, stated that study's "clear message is that there's no reason for older women to be taking combination hormone therapy."

63. **Quality of Life benefits**, On March 17, 2003, the New England Journal of Medicine (NEJM) released a follow-up WHI study which reported that hormone therapy failed to improve the quality of life for menopausal women. The Quality of Life study examined the same pool of 16,000 WHI women and found that hormone therapy drugs do not provide the very benefit that encourages women to take the treatment — that is, to make them feel happier and healthier after menopause. A comparison of women who took hormone therapy to women given a placebo showed those women taking hormones did not report sleeping better or feeling better. The hormone therapy group also did not report less depression or more sexual satisfaction than the placebo group. According to the study's lead author, Dr. Jennifer Hays: "It's just not something that's going to make most women feel better. Even if it reduces your symptoms, that's not going to translate into a meaningful effect on a quality of life."

64. For years, Manufacturing Defendants have promoted hormone therapy as drugs of prevention as well as being safe and effective. The reality is the exact opposite.

65. In the face of the now published independent studies, it is clear that the warnings and labels provided by Manufacturing Defendants were inadequate, misleading, and inaccurate. Manufacturing Defendants minimized the risks of these drugs to the prescribing physicians and ultimate users while simultaneously exaggerating the purported benefits. Physicians and patients had no ability to conduct a realistic risk versus benefit assessment.

66. Manufacturing Defendants provided inadequate warnings concerning hormone therapy as to breast cancer. Indeed, while the Prempro warning mentioned the risk of breast cancer with conjugated estrogens (the Premarin component of Prempro), it also emphasized that, with regard to the effect of added progestins on the risk of breast cancer: "The overall incidence of breast cancer does not exceed that expected in the general population." The WHI study plainly reveals that this warning is false and was known or should have been known by Wyeth and all other Manufacturing Defendants for decades.

67. Manufacturing Defendants provided inadequate warnings concerning hormone therapy as to blood clots. The Prempro warnings specifically minimized the risks of thromboembolic disorders, pulmonary embolisms and venous blood clots with language such as "the increased risk [of venous thromboembolism] was found only in current ERT [i.e., Premarin only] users", "postmenopausal estrogen use does not increase the risk of stroke" and simply "embolic cerebrovascular events and myocardial infarctions have been reported," without disclosing the true nature of the risk.

68. Manufacturing Defendants provided inadequate warnings concerning hormone therapy as to cardiac damage. For example, under Precautions, the Prempro label acknowledges:

"The effects of estrogen replacement therapy on the risk of cardiovascular disease have not been adequately studied." Nevertheless, Wyeth had long promoted the benefits of long term hormone therapy for cardiovascular disease.

69. Manufacturing Defendants represented that hormone therapy was safe for long-term use. It was not until January 6, 2003 that Wyeth abandoned this long-standing marketing strategy and cautioned physicians in a "Dear Doctor" letter that "estrogens and estrogens plus progestin should be prescribed for the shortest duration consistent with treatment goals. In early June 2003, Wyeth brought their new marketing campaign to the public with a new public relations campaign consisting of full-page advertisements placed in 180 newspapers nationwide. The advertisement, styled as "A Message from Wyeth," revealed Wyeth abandonment of its long-term strategy of promoting long-term usage of Premarin and Prempro for post-menopausal women for a variety of conditions, stating in part, that:

> Hormone therapy is not a lifelong commitment…. As a result of recent studies, we know that hormone therapy should not be used to prevent heart disease. These studies also report an increased risk of heart attack, stroke, breast cancer, blood clots, and dementia. Therefore, it is recommended that hormone therapy (estrogen, either alone or with progestin) ***should be taken for the shortest duration*** at the lowest effective dose.

70. Manufacturing Defendants represented that hormone therapy was safe at the dosages recommended over the years even though Defendants knew for years that lower doses of these medications was just as effective and with less risk. It was again not until 2003, that Manufacturing Defendants including Wyeth cautioned physicians to use the lowest possible dose. Indeed, Wyeth created an entire new marketing strategy called "Go low with Prempro" and launched a new, lower dose combination treatment.

71. Manufacturing Defendants represented that hormone therapy had benefits that were not supported by reliable science and failed to conduct the necessary pre-approval research and post-approval surveillance to establish the safety of long-term hormone therapy regimen. It was left to independent studies to uncover the serious risks that Manufacturing Defendants knew about (or in the exercise of reasonable care could have known about) these drugs. Manufacturing Defendants never told physicians and patients that no long-term testing had not been performed on these drugs, thereby fraudulently inducing physicians and patients alike to use these products with the false assumption that such drugs had been sufficiently tested.

72. The manufacturers of generic equivalent MPA as well as brand-name Provera and Cycrin were aware that MPA would be prescribed as a part of combination hormone therapy. Indeed, Manufacturing Defendants marketed, promoted and sold their MPA for such combination use. Manufacturing Defendants knew, or in the exercise of reasonable care should have known, that the synthetic progestin was harmful, defective in design, would exaggerate or accelerate the harmful effects of estrogen and the combination therapy of estrogen with MPA would be unreasonably dangerous for use. In fact, MPA, when used in combination hormone therapy has deleterious effects, including increasing the incidence of strokes, blood clots, heart attacks, breast cancers, and ovarian cancer. Even though Manufacturing Defendants knew of these risks, they did not warn consumers of the serious adverse side effects of this form of combination hormone therapy in any of their respective labels or promotional materials.

73. Further Manufacturing Defendants in their manufacture of generic equivalent and brand-name MPA failed to conduct adequate pre-marketing clinical testing and research to determine the safety of MPA when used in combination with estrogenic compounds like Premarin.

74. Manufacturing Defendants also failed to conduct adequate post-marketing surveillance to determine the safety of MPA when used in combination with estrogenic compounds.

75. Nevertheless, Manufacturing Defendants never disclosed on their respective warning labels that such testing had not been performed, thereby fraudulently inducing physicians and patients alike to use the MPA drugs with the false assumption that such drugs had been sufficiently tested.

CAUSES OF ACTION

COUNT I
NEGLIGENCE

76. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

77. At all relevant times, Manufacturing Defendants had and continue to have a duty to exercise reasonable care to properly prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell their hormone therapy drugs, which they introduced into the stream of commerce, including a duty to insure their hormone therapy drugs do not cause users to suffer from unreasonably dangerous or untoward adverse side effects.

78. At all times relevant, Manufacturing Defendants owed a duty to properly warn consumers of the risks, dangers, and adverse side effects of their hormone therapy drugs.

79. Manufacturing Defendants breached this duty by failing to exercise ordinary care in the preparation, design, research, development, manufacturing, inspection, labeling, marketing, promotion, and selling of their hormone therapy drugs, which they introduced into the stream of commerce, because Manufacturing Defendants knew or should have known that their

hormone therapy drugs created an unreasonable risk of harm for those who used the drugs.

80. Manufacturing Defendants knew, or in the exercise of reasonable care, should have known that their hormone therapy drugs, were of such a nature that, if not properly prepared, designed, researched, developed, manufactured, inspected, labeled, marketed, promoted, and sold, they were likely to cause injury to those who took their drugs.

81. Manufacturing Defendants negligently provided inadequate and inaccurate warnings and information to the medical community and the public at large, including plaintiff, by making false representations about the safety of their products. Manufacturing Defendants downplayed, understated, and disregarded their knowledge of the serious and permanent side effects associated with the use of their hormone therapy drug despite available information demonstrating that their products were likely to cause serious and sometimes fatal side effects to users.

82. Manufacturing Defendants were negligent in the preparation, design, research, development, manufacturing, inspection, labeling, marketing, promotion, and selling of their hormone therapy drugs, in that Manufacturing Defendants:

a) Failed to use due care in the preparation of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

b) Failed to use due care in the design of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

c) Failed to conduct adequate pre-clinical testing and research to determine the safety of the hormone therapy drugs;

d) Failed to conduct adequate post-marketing surveillance to determine the safety of the hormone therapy drugs;

e) Failed to accompany the hormone therapy products with proper warnings regarding all possible adverse side effects associated with the use of such products and the comparative severity and duration of such adverse effects;

f) Failed to use due care in the development of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

g) Failed to use due care in the manufacture of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

h) Failed to use due care in the inspection of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

i) Failed to use due care in the labeling of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

j) Failed to use due care in the marketing of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

k) Failed to use due care in the promotion of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

l) Failed to use due care in the selling of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

m) Failed to provide adequate training and information to healthcare providers for the appropriate use of the hormone therapy drugs;

n) Failed to warn the plaintiff and the healthcare providers, prior to actively encouraging and promoting the sale of the hormone therapy drugs, either directly or indirectly, orally or in writing, about the following:

- the need for comprehensive, regular medical monitoring to insure early discovery of potentially fatal strokes, heart attacks, venous thromboembolism, cardiovascular disease, breast cancer, ovarian cancer, and other adverse side effects; and

- the possibility of becoming disabled as a result of the use of the drugs;
- the adverse side effects associated with the use of the drug, including, but not limited to, strokes, heart attacks, venous thromboembolism, cardiovascular disease, breast cancer, and ovarian cancer; and,

o) Were otherwise careless and negligent.

83. Despite the fact that Manufacturing Defendants knew or should have known that the hormone therapy drugs caused unreasonable and dangerous side effects which many users would be unable to remedy by any means, Manufacturing Defendants continued to promote and market such products to consumers, including plaintiff, when safer and more effective methods of countering any health effects of menopause were available.

84. Manufacturing Defendants knew or should have known that consumers such as the plaintiff would foreseeably suffer injury as a result of its failure to exercise ordinary care as described herein.

85. Manufacturing Defendants knew or should have known that the hormone therapy products caused serious side effects. Nevertheless, Manufacturing Defendants continued to market such products by providing false and misleading information with regard to the safety and efficacy of the products.

86. As a result of Manufacturing Defendants' conduct, plaintiff suffered the injuries and damages specified herein. All of the Manufacturing Defendants are liable to the Plaintiff jointly and severally for all general, special, and equitable relief to which the Plaintiff is entitled by law.

87. Manufacturing Defendants' actions, described above were performed willfully, intentionally, with malice and / or with reckless disregard for the rights of plaintiff and the public. As such, Plaintiff is entitled to punitive damages against Manufacturing Defendants.

COUNT II

STRICT PRODUCTS LIABILITY
(Defective Product)

88. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

89. Plaintiff alleges that Manufacturing Defendants are liable under the theory of Strict Product Liability as set forth in the RESTATEMENT (SECOND) OF TORTS § 402A. Such Defendants were at all times engaged in the business of manufacturing, creating, designing, testing, labeling, packaging, supplying, marketing, promoting, selling, advertising, warning, and otherwise distributing hormone therapy drugs in interstate commerce, which they sold and distributed throughout the United States.

90. Hormone Therapy drugs were expected to and did reach the Plaintiff without substantial change in its condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned and otherwise distributed.

91. Plaintiff used hormone therapy in a manner for which it was intended or in a reasonably foreseeable manner.

92. Manufacturing Defendants' hormone therapy caused increased risks of personal injury and harm upon consumption, and therefore constitute a product unreasonably dangerous for normal use due to their defective design, defective manufacture, and the Defendants' misrepresentations and inadequate facts disclosed to the Plaintiff.

93. The hormone therapy drugs manufactured and/or supplied by Manufacturing Defendants were defective due to:

(a) Defective design or formulation in that when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation;

(b) Defective marketing in that Defendants made inappropriate, misleading, inaccurate and incomplete representations about this product in advertisements, news, commercials, and direct to consumer advertisements. These deceptive marketing representations were made to the FDA, healthcare providers, pharmacists and the public. These deceptive marketing representations were made in order to induce sales and increase profits;

(c) Defective design or formulation, in that when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect, and more dangerous than other hormone replacement therapy (HRT) medications;

(d) Inadequate warnings or instructions because the defendants knew or should have known that the product created a risk of dangerous side effects and other related conditions and diseases;

(e) Inadequate pre-marketing testing which, if conducted properly, would have revealed the serious problems with this drug prior to the first sale; and/or

(f) Inadequate post-marketing warning or instruction because, after the defendants knew or should have known of the risk of dangerous side effects and other related conditions and diseases, they failed to provide adequate warnings to users or consumers of the product and continued to promote the product.

94. Manufacturing Defendants, therefore, are strictly liable to the Plaintiff.

95. As a direct and proximate result of these Defendants' manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distribution of hormone therapy drugs in interstate commerce, Plaintiff has suffered injury and is at an increased risk of developing further injuries and has suffered compensatory and punitive damages in an amount to be proven at trial.

96. Manufacturing Defendants' actions, described above were performed willfully, intentionally, with malice and / or with reckless disregard for the rights of plaintiff and the public. As such, Plaintiff is entitled to punitive damages against Manufacturing Defendants.

COUNT III

STRICT PRODUCTS LIABILITY

(Defective Marketing and Inadequate Warnings)

97. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

98. Manufacturing Defendants are manufacturers and/or suppliers of hormone therapy using retail or sample distribution. The hormone therapy manufactured and/or supplied by Manufacturing Defendants were not accompanied by proper warnings regarding dangerous side effects and posed potentially fatal health risks associated with the use of hormone therapy drugs in that the warnings given did not accurately reflect the symptoms, scope or severity of such injuries and health risks.

99. Manufacturing Defendants failed to effectively warn consumers, pharmacists, physicians and healthcare providers that even under close medical monitoring, the potential for serious health complications existed, and there was no way to know which patients would suffer such complications.

100. Manufacturing Defendants failed to perform adequate testing in that adequate testing would have shown that hormone therapy drugs pose significant risks of serious health events including and related conditions and diseases, with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made.

101. Manufacturing Defendants knew, or should have known, that hormone therapy drugs were dangerously defective products which pose unacceptable risks unknown and unknowable by the consuming public of serious health events and related conditions and diseases. The hormone therapy drugs were defective due to inadequate warnings because after the Defendants knew or should have known of the risk of dangerous side effects and potentially fatal health risks, they failed to provide adequate warnings to consumers of the product and continued to aggressively promote and market the dangerously defective drugs.

102. As a direct and proximate result of Manufacturing Defendants' conduct, Plaintiff has suffered injury and is at an increased risk of developing further injuries and has suffered compensatory and punitive damages in an amount to be proven at trial.

103. Manufacturing Defendants' actions, described above were performed willfully, intentionally, with malice and / or with reckless disregard for the rights of plaintiff and the public. As such, Plaintiff is entitled to punitive damages against Manufacturing Defendants.

COUNT IV
BREACH OF EXPRESS WARRANTY

104. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

105. Manufacturing Defendants, through description, affirmation of fact, and promise expressly warranted to the FDA, prescribing physicians, and the general public, including the plaintiff, that their hormone therapy products were both efficacious and safe for the intended use. These warranties came in the form of:

(i) Publicly-made written and verbal assurances of the safety and efficacy of hormone therapy drugs,

(ii) Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create and increase demand for hormone therapy drugs, which utterly failed to warn of the risks inherent to the ingestion of such products;

(iii) Verbal assurances made by Manufacturing Defendants regarding hormone therapy, and the downplaying of any risk associated with the drug;

(iv) False and misleading written information, supplied by Manufacturing Defendants, and published in the *Physicians Desk Reference* on an annual basis, upon which physicians were forced to rely in prescribing hormone therapy drugs during the period of plaintiff's ingestion of hormone therapy drugs, including, but not limited to information relating the recommended dose, administration and duration of the use of the drugs;

(v) Promotional pamphlets and brochures published and distributed by Manufacturing Defendants and directed to consumers; and

(vi) Advertisements.

The documents referred to in this paragraph were created by and at the direction of Manufacturing Defendants.

106. At the time of these express warranties, Manufacturing Defendants had knowledge of the purpose for which hormone therapy was to be used and warranted it to be in all aspects safe, effective, and proper for such purpose. Manufacturing Defendants' hormone therapy drugs do not conform to these express representations in that they are neither safe nor effective and use of such drugs produce serious adverse side effects.

107. As such, Manufacturing Defendants' products were neither in conformity to the promises, descriptions or affirmations of fact made about these drugs nor adequately contained, packaged, labeled or fit for the ordinary purposes for which such goods are used.

108. Manufacturing Defendants breached their express warranties to plaintiff by:

(i) Manufacturing, marketing, packaging, labeling, and selling hormone therapy to the plaintiff in such a way that misstated the risks of injury, without warning or disclosure thereof by package and label of such risks

to the plaintiff or the prescribing physician or pharmacist, or without so modifying or excluding such express warranties;

(ii) Manufacturing, marketing, packaging, labeling, and selling hormone therapy to plaintiff, which failed to counteract the negative health effects of menopause in a safe and permanent manner and without injury; and

(iii) Manufacturing, marketing, packaging, labeling, and selling hormone therapy to plaintiff, thereby causing the plaintiff serious physical injury and pain and suffering.

109. As a direct and proximate result of Manufacturing Defendants' conduct, Plaintiff has suffered injury and is at an increased risk of developing further injuries and has suffered compensatory and punitive damages in an amount to be proven at trial.

110. Manufacturing Defendants' actions, described above were performed willfully, intentionally, with malice and / or with reckless disregard for the rights of plaintiff and the public. As such, Plaintiff is entitled to punitive damages against Manufacturing Defendants.

COUNT V
NEGLIGENT MISREPRESENTATIONS

111. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

112. At the time the Manufacturing Defendants manufactured, designed, marketed, sold, and distributed hormone therapy drugs for use by the Plaintiff, Manufacturing Defendants knew or should have known of the use for which hormone therapy drugs were intended and knew or should have known of the serious risks and dangers associated with such use of these products.

113. Manufacturing Defendants owed a duty to prescribing physicians and ultimate end users, including Plaintiff to accurately and truthfully represent the risks and benefits of hormone therapy drugs. Manufacturing Defendants breached that duty by misrepresenting the

risks and benefits of hormone therapy drugs to the prescribing physicians and ultimate users, including the Plaintiff.

114. As a direct and proximate result of Manufacturing Defendants' conduct, Plaintiff has suffered injury and is at an increased risk of developing further injuries and has suffered compensatory and punitive damages in an amount to be proven at trial.

115. Manufacturing Defendants' actions, described above were performed willfully, intentionally, with malice and / or with reckless disregard for the rights of plaintiff and the public. As such, Plaintiff is entitled to punitive damages against Manufacturing Defendants.

COUNT VI

FRAUD

116. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

117. Manufacturing Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell their hormone therapy drugs owed a duty to provide accurate and complete information regarding these products.

118. Manufacturing Defendants' advertising program, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of their hormone therapy drugs were safe for human use, had no unacceptable side effects, and would not interfere with daily life.

119. Manufacturing Defendants intentionally encouraged consumers and plaintiff to remain on hormone therapy for a longer duration than they know or should have known were safe and effective to remain on such products and at higher dosage levels than necessary.

120. On information and belief, Plaintiff avers that Manufacturing Defendants purposefully concealed, failed to disclose, misstated, downplayed, and understated the health hazards and risks associated with the use of hormone therapy. Manufacturing Defendants, through promotional practices as well as the publication of medical literature, deceived potential users and prescribers of the drugs by relaying only allegedly positive information, while concealing, misstating, and downplaying the known adverse and serious health effects. Manufacturing Defendants falsely and deceptively kept relevant information from potential hormone therapy users and minimized prescriber concerns regarding the safety and efficacy of their drugs.

121. Manufacturing Defendants did not properly study nor report accurately the results of its human animal and cell studies in terms of risks and benefits of its hormone therapy drugs. Manufacturing Defendants also fraudulently and intentionally polluted the scientific literature related to hormone therapy in general and its hormone drugs in particular. Manufacturing Defendants hired physicians and scientists to write inaccurate and misleading scientific articles for the purpose of creating confusion so as to pollute existing scientific and medical knowledge pertaining to menopausal hormone therapy and its particular products. Manufacturing Defendants then used and relied on these inaccurate and fraudulently prepared scientific papers to defend and justify the marketing, promotions, and labeling of its hormone products. At all times, Manufacturing Defendants knew that what it was publishing or having published was inaccurate and that this information would mislead the members of the medical and scientific communities who were studying or more importantly, prescribing the hormone drugs.

122. The scientific and medical communities were misled as to the true nature of the risk and benefits of the Manufacturing Defendants' hormone therapy products in particular and

in general as to the treatment needs and options for the symptoms of menopause. It was not until the publication of the results from the independent study conducted by the WHI that the truth began to be generally available. Even then the doctors in those communities had been so conditioned by the false science published and or funded for years by Manufacturing Defendants that it was difficult for many of those doctors to accept the truth about the risks and lack of benefits associated with these hormone drugs.

123. The misconceptions as to the true risks and benefits of Manufacturing Defendants' hormone drugs were pervasive throughout the medical and scientific communities due to the marketing methods employed by Manufacturing Defendants that included but were not limited to the following:

- The publication of fraudulent scientific papers in scientific and medical literature;
- Providing false and misleading information to doctors during sales and detailing calls at the doctors offices or at medical or scientific conferences and meetings;
- Funding third-party organizations to disseminate false and misleading scientific and medical information through its publications and its members to physicians and patients;
- Funding continuing medical education to disseminate false and misleading information to doctors;
- Paying specialists in the hormone and menopause field to meet with prescribing doctors for the purpose of disseminating false and misleading information about the risks and benefits of the drugs;
- Providing false and misleading information to the FDA to support inaccurate risk and benefit information contained in the product labeling; and
- Disseminating direct to consumers advertising to drive patients to their doctors' offices to ask for the drugs based on false and misleading information regarding the risks and benefits of the drugs.

124. In particular, in the materials disseminated by Manufacturing Defendants, they falsely and deceptively misrepresented or omitted a number of material facts regarding their hormone replacement drugs, including, but not limited to, the following:

- The presence and adequacy of the testing of the hormone therapy drugs, both pre-and post-marketing;
- The severity and frequency of adverse health effects caused by the hormone therapy drugs;
- The range of injuries caused by the hormone therapy drugs; and
- The lack of any reliable science to support representations about the benefits of hormone therapy.

125. As a result of these efforts it was accepted by the medical and scientific communities that these hormone drugs had a certain risk benefit profile that was shown to be completely false by independent studies including the WHI.

126. Manufacturing Defendants were in possession of evidence demonstrating that the hormone therapy products caused serious side effects. Nevertheless, Manufacturing Defendants continued to market such products by providing false and misleading information with regard to its safety and efficacy to Plaintiff and Plaintiff's treating physicians.

127. Plaintiff and Plaintiff's treating physician(s) justifiably relied to their detriment on Manufacturing Defendants' intentional and fraudulent misrepresentations as set out above concerning their hormone therapy drugs.

COUNT VII

GENERAL DAMAGES

128. Plaintiff has been injured in many ways as a result of Defendants' actions. Plaintiff is alleging and can prove serious health problems associated with the use of hormone therapy drugs as described above.

129. Plaintiff suffered from breast cancer, she has suffered in the past, and it is anticipated will suffer in the future, medical testing, breast biopsies, invasive exploratory surgeries, removal of breast tissue, lumpectomy or mastectomy surgeries, disfigurement, reconstruction surgeries, chemotherapy, radiation, chemical treatments, long-term cancer treatment using anti-estrogen drugs, continuing medical monitoring, physical and emotional pain, physical and emotional suffering, mental anguish, physical impairment, medical bills and expenses as well as loss of wages and wage earning capacity.

COUNT VIII

GROSS NEGLIGENCE

130. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges the following:

131. The wrong done by the Defendants was aggravated by the kind of malice, fraud, reckless disregard for the rights of others, the public and the Plaintiff and conduct for which the law allows the imposition of exemplary damages, in that the Defendants' conduct:

- Specifically intended to cause substantial injury to the Plaintiff; or
- When viewed objectively from Defendants' standpoint a the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved,

but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or

- Made a material representation that was false, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation be acted on by the plaintiff. The Plaintiff relied on the representation and suffered injury as a result of this reliance.

132. Plaintiff, therefore, seeks exemplary damages in an amount within the jurisdictional limits of the court. Plaintiff also alleges that the acts and omissions of the named Manufacturing Defendants whether taken singularly or in combination with others, constitute gross negligence which proximately caused the injuries to Plaintiff. In that regard, Plaintiff seeks exemplary damages in an amount which would punish such Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT IX

CLAIM FOR EXEMPLARY DAMAGES/PUNITIVE DAMAGES

133. Plaintiff incorporates all preceding paragraphs as if fully set forth herein and further alleges as follows:

134. As set forth in each and every claim of relief, Plaintiff alleges that the acts and omissions of Pharmaceutical Defendants whether taken singularly or in combination with others, constitute fraud, reckless disregard for the safety of the public and the Plaintiff, malice, and/or gross neglect for which the Defendants should each be assessed punitive damages in an amount in excess of $20 million ($20,000,000) so as to discourage future acts of such nature.

COUNT VI
APPLICATION OF THE DISCOVERY RULE

135. The nature of Plaintiff's injuries and the relationship of such injuries to Hormone Replacement Drugs were inherently undiscoverable prior to Defendants' public dissemination of risk information in July of 2002.

136. Accordingly, the discovery rule should be applied to toll the running of the stature of limitations until Plaintiff knew, or through reasonable care and diligence should have known, of their claims against Defendants. Plaintiff did not discover, and through the exercise of reasonable care and due diligence should not and could not have discovered, their illnesses and injuries or their relationship to the HRT drugs until after July of 2002.

137. Furthermore, prior to July 2002, Plaintiff did not have knowledge of the facts that would lead a reasonably prudent person to make inquiry to discover Defendants' tortious conduct. Plaintiff's suit was filed well within the applicable statute of limitations period under appropriate application of the "discovery rule."

138. In the alternative, the facts of Plaintiff's claims made it impossible for them to discover their injuries and causes of action within the applicable limitations period. Plaintiff filed this lawsuit within the applicable limitations period of the date they knew or through the exercise of reasonable care and due diligence should have known of their claim.

COUNT VII

FRAUDULENT CONCEALMENT

139. Defendants are stopped from asserting a statute of limitations defense because they fraudulently concealed their wrongful conduct from the Plaintiff. First, Defendants had actual knowledge of the defective and dangerous nature of the HRT drugs. Second, Defendants

failed to conduct adequate testing on their products to establish safety and efficacy. Third, Defendants had actual knowledge of their misrepresentations, negligence, breach of warranties, and false, misleading, deceptive, and unconscionable conduct. Yet, each of the Defendants continued to perpetuate their wrongful conduct with the intent and fixed purpose of concealing their wrongs from the Plaintiff and the public at large.

140. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by all Manufacturing Defendants. Plaintiff has been misled and denied access to vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiff could not reasonably have discovered the dangerous nature of and unreasonable adverse side effects associated with the use of the combination hormone therapy prior to July of 2002, at the earliest.

141. Manufacturing Defendants were under a continuing duty to disclose the true character, quality, and nature of their hormone therapy drugs, including an accurate account of all risk and all benefits. Because of their active concealment of the true character, quality and nature of their hormone therapy drugs, Manufacturing Defendants are stopped from relying on any statute of limitations defense as a bar to Plaintiff's claim.

COUNT VIII

ALTER EGO/CORPORATE LIABILITY/ CIVIL CONSPIRACY

142. At all times herein mentioned, each of the "Defendants" or "Manufacturing Defendants" was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venture of each of the other defendants herein and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint

venture and rendered substantial assistance and encouragement to the other defendants, knowing that their conduct constituted a breach of duty owed to plaintiff.

143. Defendants entered into a civil conspiracy and agreements whereby they created an atmosphere of misrepresentations and deceit which allowed each Defendant to sell hormone therapy drugs without adequate warnings to the prescribing physicians and patients.

144. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain defendants and other certain defendants such that any individuality and separateness between the certain defendants has ceased and these defendants are the alter ego of the other certain defendants and exerted control over those defendants. Adherence to the fiction of the separate existence of these certain defendants as an entity distinct from other certain defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

145. At all times herein mentioned the defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling HRT medications for the use and ingestion by plaintiff and all other users. As such each Defendant is both individually, jointly and severally liable to the Plaintiff for the Plaintiff's damages.

146. At all times herein mentioned, the officers and/or directors of the corporate defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said

products and thereby actively participated in the tortious conduct which resulted in the injuries suffered by plaintiff.

WHEREFORE, Plaintiff prays for judgment against the Defendants jointly and severally in an amount to compensate Plaintiff fully for their injuries and in an amount above the minimal jurisdictional limits of this Court, for prejudgment and post-judgment interest, for attorney fees if appropriate, for the costs of this action and for such other relief as the Court may deem just and equitable.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury on all questions of fact raised by the Complaint.

Dated: December 22, 2010

Respectfully submitted,

FOOTE, MEYERS, MIELKE & FLOWERS LLC

/s/Peter J. Flowers, Esq.

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